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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/092,640

03/05/2002

James D. Marks

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EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/092,640

Applicant(s)

MARKS ET AL.

Examiner

Hong Sang

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,24-26,28,41 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,24-26,28,41 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Marks et al.

1. Applicant's response filed on 4/18/06 is acknowledged. Claims 21, 22, 24-26, 28, 41 and 45 are pending. Claims 1-20, 23, 27, 29-40, 42-44, and 46-50 are cancelled. Claims 21, 28, and 45 are amended.
2. Claims 21, 22, 24-26, 28, 41 and 45 are under examination.

Objections Withdrawn

3. The objection to claims 28 and 45 is withdrawn in view of applications' amendment to the claims.
4. The objection to claim 45 as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim are withdrawn in view of applications' amendment to the claims.

Rejections Withdrawn

5. The rejection of claims 21-22, 24-26, 28, 41, and 45 under 35 U.S.C. 102(a) as being anticipated by Schier et al. (Immunotechnology 1:73-81, 1995) is withdrawn in view of applicants' submission of Declaration under 47 C.F.R. §1.132.

6. The rejection of claims 21, 22, 24, 25, 28 and 45 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a human C6 antibody that specifically binds to C-erbB-2, wherein said C6 antibody comprises the variable heavy (V_H) chain of C6.5 (SEQ ID NO.32) and the variable light (V_L) chain of C6.5 (SEQ ID NO.36), does not reasonably provide enablement for an isolated nucleic acid encoding a human C6 antibody that specifically binds to C-erbB-2, wherein said C6 antibody comprises the variable heavy (V_H) chain of C6.5 (SEQ ID NO.32) or the variable light (V_L) chain of C6.5 (SEQ ID NO.36), the nucleic acid of claim 21, wherein said nucleic acid encodes the variable light (V_L) chain of C6.5, and the nucleic acid of claim 21, wherein said nucleic acid encodes the variable heavy (V_H) chain of C6.5 is withdrawn in view of the new grounds of rejections.

New Grounds of Objections and Rejections

Claim Objections

7. Claims 24 and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 21 is drawn to an isolated nucleic acid encoding both V_H region and V_L region of a C6 antibody. Claim 24 and 25 are drawn to an isolated nucleic acid encoding a single V_H chain, or a single V_L chain of C6.5. As such claims 24 and 25 do not further limit the nucleic acid claimed in claim 21.

Claim Rejections - 35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21, 22, 24-26, 28, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "wherein the variable heavy chain"" and "and/or the variable light chain". There is insufficient antecedent basis for this limitation in the claim. Claim 21 only mentions "a variable heavy (VH) region" and "a variable light (VL) region."

Claim Rejections - 35 USC § 112, 1st paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 21, 22, 24, 25, 28, 41 and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a human C6 antibody that specifically binds to C-erbB-2, wherein said C6 antibody comprises the variable heavy (V_H) chain of C6.5 (SEQ ID NO.32) and the variable light (V_L) chain of C6.5 (SEQ ID NO.36), does not reasonably provide

enablement for an isolated nucleic acid encoding a human C6 antibody that specifically binds to C-erbB-2, wherein said C6 antibody comprises a VH region of the VH chain of C6.5 (SEQ ID NO.32) and the VL region of the VL chain of C6.5 (SEQ ID NO.36), and a nucleic acid molecule encoding a single chain polypeptide that exhibits the antibody-binding specificity of a human C6 antibody, said polypeptide comprising the binding portion of a variable region of a heavy chain of C6.5 (SEQ ID NO. 32) and the binding portion of a variable region of a light chain of C6.5 (SEQ ID NO. 36).

The response states that claim 1 has been amended to a nucleic acid comprising both a VH and a VL where the VH domain and/or the VL domain is a C6.5 VH or VL domain.

While claim 1 is amended to add limitation "wherein said C6 antibody comprises a variable heavy (VH) region and a variable light (VL) region", the term "region" reads on any portion of a variable chain, such as a single CDR (see specification, Table 1, and page 7, paragraph [0023]). Moreover, the specification teaches that a "binding portion" refers to the part of an immunoglobulin molecule that participates in antigen binding (see page 7, paragraph [0023]). Therefore, the "binding portion of a variable region" recited in claim 41 encompasses any portion of a variable chain that participates in antigen binding. As indicated in the previous office action that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and

light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. Because claims encompass antibody fragments that comprise any portions of a VH and a VL chain of C6.5 antibody, such as a single CDR, undue experimentation would be required to practice the claimed invention.

Conclusion

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Hong Sang, Ph.D.
Art Unit 1643
May 14, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER